REMARKS/ARGUMENTS

Claims 34 – 36 and 38 – 50 are pending in the application. Claim 37 has been canceled by this Amendment and incorporated into claim 34.

In response to the restriction requirement, Applicants elect **Group I, claims 34 – 45**, with traverse, for the reasons below. Claims 46 – 50 are withdrawn in response to the restriction requirement. However, Applicants respectfully request rejoinder of dependent claims 46 – 50 in the event that the elected claims are allowable.

In addition, in response to the requirement for an election of species, Applicants respectfully elect the device in claim 39; i.e., containing between 0.5 wt% and 30 wt% of rifaximin, 10 wt% of polyvinylalcohol and between 0.2 wt% and 20 wt% of acrylic polymer.

Claim 34 is amended by this Amendment to add a range of wt%'s for rifaximin (disclosed at page 3, lines 31 – 32), and by adding polyvinylalcohol (previously set forth in claim 37, now canceled). Claim 47, which is withdrawn in accordance with the restriction requirement, is amended to depend from claim 34, and by amending step a) accordingly. At page 3, lines 6 – 12, there are listed a number of polymers suitable for obtaining the bi-phasic material for controlled and continued delivery of rifaximin; particularly, polyvinylalcohol is disclosed to be dissolved in water and the other components are added, as disclosed at page 3, lines 13 – 32.

Applicants respectfully traverse the restriction requirement on grounds that the claims possess a special technical feature that makes a contribution over the cited art, WO 99/015210 to Mantelle (hereinafter, "Mantelle"). Mantelle discloses bioadhesive compositions that can include any of an extensive listing of active agents, including rifaximin, but fails to disclose or even suggest a device having the particular concentration range of rifaximin and the bi-phasic material provided in claim 34; i.e., "comprising between 0.5 wt% and 30 wt% of rifaximin and a bi-phasic material, wherein in said bi-phasic material the solid phase is an elastic polymeric matrix comprising polyvinylalcohol, and the liquid phase is water that fills up the pores of said matrix." Thus, claim 34 possesses novelty and inventive step over Mantelle.

Furthermore, Mantelle does not address at all the technical problem that is addressed by the current application; i.e., the problem related to the use and administration of rifaximin, due to the very low solubility of rifaximin in physiological fluids. The present device "allows high level, constant in time, of concentration of rifaximin in aqueous body fluids avoiding the intense red color that it produces in the neighboring of the place of [administration]." (page 2, lines 24 – 26).

In view of the above, Applicants submit that claim 34 and its dependent claims possess a special technical feature for controlled local delivery of rifaximin that makes a clear and significant contribution over Mantelle, and thereby possess unity of invention. Accordingly, Applicants respectfully request reconsideration and withdrawal of the restriction requirement.

Since non-elected claims 46 – 50 include all limitations of the elected claims, Applicants respectfully request rejoinder of claims 46 – 50 in the event that the elected product claims are allowable.

Applicants submit that the claims of the present application are in condition for allowance. Accordingly, Applicants respectfully request rejoinder of non-elected claims 46 – 50, and passage of claims 34 – 36 and 38 – 50 to allowance.

Respectfully submitted,

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